



Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10792, CMS-10793, and CMS-367a – e]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number: _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html).

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10792 Patient-Reported Indicator Survey (PaRIS)

CMS-10793 Medicare Advantage and Prescription Drug Plan Consumer Assessment of
Healthcare Providers and Systems (CAHPS) Survey Field Test

CMS-367a – e Medicaid Drug Rebate Program Labeler Reporting Format

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit

reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Patient-Reported Indicator Survey (PaRIS); *Use:* The Centers for Medicare and Medicaid Services (CMS) invites comments on a proposed new Information Collection Request (ICR) to conduct the International Survey of People Living with Chronic Conditions (hereafter referred to as the PaRIS Survey). This survey has been developed by a collaborative workgroup under the auspices of the Organization for Economic Cooperation and Development (OECD), an international organization that works with governments, policy makers, and citizens to shape policies that foster prosperity, equality, opportunity, and well-being for all.

The OECD launched the PaRIS initiative in 2017 to address gaps in health outcomes measures, particularly regarding user experiences with health care services. OECD member countries, including the U.S., are working together to develop, standardize, and implement indicators that measure outcomes and experiences of health care that matter most to people. The PaRIS Survey will provide a common set of measures that support policy makers across participating countries to improve health care delivery. On behalf of the Department of Health and Human Services (DHHS) Assistant Secretary for Planning and Evaluation (ASPE), the Office of Enterprise Data and Analytics (OEDA) in CMS has been designated as the lead participant for the U.S.

The PaRIS Survey will help to close critical policy gaps by focusing on: (1) Patient Reported Experience Measures (PREMS) which measure how patients experience health care,

and (2) Patient Reported Outcome Measures (PROMS) which measure how patients assess the results of the care they receive. The PaRIS survey includes both PREMS and PROMS items and aims to collect vital information about primary health care, by asking about topics such as the respondent's health, health behaviors, patient activation and confidence in managing their health care, experiences with health care and health providers including access to health care, quality of life, physical functioning, and psychological well-being.

OECD and its member countries will use data collected by the PaRIS Survey to shed light on key questions about how well care in each country is organized around the needs of patients. Results from the survey will show how key outcomes and experiences vary across and within countries. This will allow countries to benchmark and learn from each other's approaches. The survey will also help policy makers in OECD member countries understand how health systems are addressing the needs of persons with chronic health conditions. Findings will foster a dialogue with service providers about how to further improve the performance and people-centeredness of primary health care services.

To facilitate U.S. participation in this important initiative, CMS will leverage the existing sample for the Medicare Current Beneficiary Survey (MCBS). The MCBS is a continuous, multi-purpose survey of a representative national sample of the Medicare population, including the population of beneficiaries aged 65 and over and beneficiaries aged 64 and below with certain disabling conditions, residing in the U.S.; it is conducted under OMB clearance number 0938-0568. Given the age and health characteristics of Medicare beneficiaries, the MCBS sample will provide a comparable population to survey respondents selected in other participating OECD countries. Interviewers will telephone MCBS respondents and administer the PaRIS Survey by phone as a one-time standalone survey during January through April 2023. Non-response follow-up will be conducted by telephone and in-person as needed. It is estimated that 7,559 Medicare beneficiaries will participate in this 40-minute survey. CMS plans to release a disclosure protected public use file with accompanying methodological documentation. This

public use file will also be made available to OECD for analysis and released with data from other participating countries. *Form Number:* CMS-10792 (OMB: 0938-New); *Frequency:* One-time collection; *Affected Public:* Individuals residing in households; *Number of Respondents:* 7,559; *Total Hours:* 5,065 (For policy questions regarding this collection contact William Long at 410-786-7927.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Advantage and Prescription Drug Plan Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey Field Test; *Use:* CMS is required to collect and report information on the quality of health care services and prescription drug coverage available to persons enrolled in a Medicare health or prescription drug plan under provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Specifically, the MMA under Sec. 1860D-4 (Information to Facilitate Enrollment) requires CMS to conduct consumer satisfaction surveys regarding Medicare PDPs and MA plans and report this information to Medicare beneficiaries prior to the Medicare annual enrollment period. The Medicare CAHPS survey meets the requirement of collecting and publicly reporting consumer satisfaction information.

Currently, the MA & PDP CAHPS Surveys (0938-0732) are administered using a mixed mode data collection protocol (mail+phone) that includes two survey mailings and phone follow-up with non-respondents. This request is to conduct a field test with the main goal of testing the effects of new survey content and a web-based mode on patterns of response and survey scores. The test will also allow for assessment of the measurement properties of new survey items. The results of the field test will inform CMS's decision-making about updates to MA & PDP CAHPS survey content and survey administration procedures. *Form Number:* CMS-10793 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 5,000; *Total Annual Responses:* 5,000; *Total Annual Hours:* 1,290. (For policy questions regarding this collection contact Lauren K. Fuentes at 410-786-2290.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate Program Labeler Reporting Format; *Use:* Labelers transmit drug product and pricing data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) and the unit rebate offset amount (UROA) for each new drug application (NDC) and distributes to all State Medicaid agencies. States use the URA to invoice the labeler for rebates and the UROA to report onto CMS-64. The monthly data is used to calculate Federal Upper Limit (FUL) prices for applicable drugs and for states that opt to use this data to establish their pharmacy reimbursement methodology. In this November 2021 iteration, CMS-367d (Manufacturer Contact Form) is being revised to include a signature/date line for the submitter to confirm that the information provide is accurate, and we have additionally updated the entire 367d to a fillable format, per multiple labeler requests. CMS-367e (Quarterly VBP-MBP Data) is a new form that is intended for manufacturers to use (as needed) on a quarterly basis, to transmit pricing data (best prices associated with value-based purchasing (VBP) arrangements) for each of their covered outpatient drugs (CODs) to CMS either via direct file upload to the MDP System or manual on-line entry. The CMS-367e form is optional. We are not proposing any changes to the CMS-367a (Quarterly Pricing), CMS-367b (Monthly Pricing), or CMS-367c (Product Data) forms. *Form Number:* CMS-367a, b, c, d, and e (OMB control number: 0938-0578); *Frequency:* Monthly, quarterly, and on occasion; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 780; *Total Annual Responses:* 15,020; *Total Annual Hours:* 564,394. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

Dated: November 3, 2021.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

[FR Doc. 2021-24393 Filed: 11/8/2021 8:45 am; Publication Date: 11/9/2021]